K131305

AUG 1 2013

PREMARKET NOTIFICATION [510(k)] Summary

This Summary of Safety and Effectiveness is prepared in accordance with 21 CFR Part 807.92(c).

1. **Company Name:**

Chison Medical Imaging Co., Ltd.
No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142
Chison Medical Imaging Co., Ltd.
No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

Contact: Ms. Ruoli Mo
Tel: +86-510-85311707, 85310593 Fax: +86-510-85310726

U.S. Agent: Leiker Regulatory & Quality Consulting
7263 Cronin Circle
Dublin, CA 94568

Contact: Bob Leiker
Tel: (925) 556-1302 Fax: (866) 718-3819

2. **Device Name:** ECO Series Diagnostic Ultrasound System

Common/Usual Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

2. Marketed Device:

K102256,GE LOGIQ e Ultrasound System

3. Device Description:

The ECO Series Diagnostic Ultrasound Systems is a very compact and portable diagnostic ultrasound system having five variations: ECO6, ECO5, ECO3, ECO2, and ECO1, each with options and features suited for its market niche. It has an integrated keyboard, LED display and several interchangeable electronic-array transducers and provides digital acquisition, processing and display capability. The user interface includes a keyboard, an intuitive layout of specialized controls, color GUI display.

The ECO Series Models, have been designed to meet the following product safety standards: NEMA UD 2, NEMA UD 3, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC 10993-1.

4. Indications for Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid);Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

Comparison to Predicate Device:

The ECO Series Models is of comparable type and substantially equivalent to the GE LOGIQ i, LOGIQ e, and the Vivid e Diagnostic Ultrasound (K102256). All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have the same intended uses and basic operating modes as the predicate device. All systems allow for specialized measurements of structures and flow, and calculations.

5. Conclusion:

The ECO Series Models is substantially equivalent in safety and effectiveness to the predicate systems. The systems are intended for diagnostic ultrasound imaging and fluid flow analysis. The systems have the same gray-scale. The systems have acoustic output levels below the applicable FDA limits. The systems are designed to applicable electrical and physical safety standards.

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2013

Chison Medical Imaging Co., Ltd.
% Mr. Bob Leiker
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
DUBLIN CA 94568

Re: K131305
Trade/Device Name: ECO Series Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 29, 2013
Received: June 28, 2013

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the ECO Series Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

C3-A	L7M-A	P3-A
MC3-A	L7S-A	MC6-A
V6-A	R7-A	

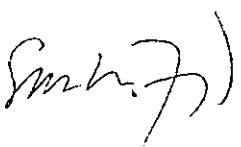
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Diagnostic Ultrasound Indications For Use

1.3 Indications for Use

510(K) Number: K131305

Device Name: ECO Series Diagnostic Ultrasound Systems

Indications for use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ(breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

Prescription Use ___×___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k) K131305

Diagnostic Ultrasound Indications For Use

System: ECO Series Diagnostic Ultrasound Systems

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal	N	N	N		N	N	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1
	Cardiac Pediatric	N	N	N		N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____K131305_____

System: ECO Series Diagnostic Ultrasound Systems
Transducer: C3-A, Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging &	Fetal	N	N	N		N	N	Note 1
Other	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) K131305

System: ECO Series Diagnostic Ultrasound Systems
Transducer: MC3-A, Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1
	Cardiac Pediatric	N	N	N		N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____K131305_____

System: ECO Series Diagnostic Ultrasound Systems
Transducer: V6-A, Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal	N	N	N		N	N	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____K131305_____

System: ECO Series Diagnostic Ultrasound Systems
Transducer: L7M-A, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) K131305

System: ECO Series Diagnostic Ultrasound Systems
Transducer: L7S-A, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____K131305_____

System: ECO Series Diagnostic Ultrasound Systems
Transducer: R7-A, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)	N	N	N		N	N	Note 1
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____K131305_____

System: ECO Series Diagnostic Ultrasound Systems
Transducer: P3-A, Phased Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1
	Cardiac Pediatric	N	N	N		N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k)_____K131305_____

System: ECO Series Diagnostic Ultrasound Systems
Transducer: MC6-A, Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology)							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N		N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+THI,B+Color Doppler+PWD, B+Power Doppler+PWD

Comments: Small Organ: Thyroid, testes and breast

Prescription Use ___×___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health
510(k) K131305